



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

HFE-35
m3037n
Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos Ave.
San Juan, PR 00901-3223

Telephone: 787-729-6894
FAX: 787-729-6658

September 9, 1999

WARNING LETTER
SJM-99-15

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Daniel Juan
President
Jack Packaging, Inc.
HC-02 Box 7071
Ciales, Puerto Rico 00638-9704

Dear Mr. Juan:

During an inspection of your food processing and packaging facility located in Ciales, PR on August 19, 1999, our inspector collected samples and labeling for your "Don Juan", "Filler", "Eric's", and "Holsum", repacked iced gem biscuits imported from Belgium. Review of the labeling of these brands revealed that your products are misbranded within the meaning of Section 403(a)(1) of the Federal Food and Drug Act (FD&C Act) as follows:

The declaration of ingredients in the labels used to repack the product, ice gem biscuits imported from Belgium, is not the same as the declaration of ingredients in the original label of the product. (See attached chart). [21 CFR 101.4]

The labels for "Don Juan", "Filler", and "Eric's", show that the ingredients are not listed in the same order as in the label of the product imported from Belgium. (See attached chart). [21 CFR 101.4]

The 5 oz. package label of the "Filler", "Eric's", and "Holsum" brands does not include the point of origin of the product (Belgium), which is required in imported products. [21 CFR 101.18]

Mr. Daniel Juan
September 9, 1999

Page 2

Another concern regarding these labels is how the discrepancies in the labeling (ingredient list) affects the Nutritional Facts Panel.

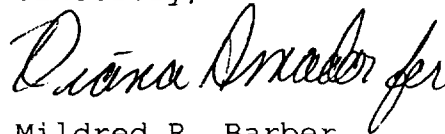
The above identification of violations is not intended to be an all-inclusive list of labeling deviations. It is your responsibility to assure adherence with all applicable labeling regulations.

Please notify the San Juan District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Daniel Gonzalez, Director, Compliance Branch.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mildred R. Barber".

Mildred R. Barber
District Director